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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/599,697 | 10/05/2006 | Jurgen Wagner | 33714-US-PCT | 2925 |
| NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080 | | | EXAM | IINER |
| | | | WEBB, WALTER E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1612 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 09/23/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief

| Application No. | Applicant(s) | |
|-----------------|---------------|--|
| 10/599,697 | WAGNER ET AL. | |
| | | |
| Examiner | Art Unit | |

| | The MAILING DATE of this communication appears on | the cover sheet with the correspondence address | |
|--|--|--|----------|
| THE R | EPLY FILED <u>01 September 2009</u> FAILS TO PLACE THIS APPL | LICATION IN CONDITION FOR ALLOWANCE. | |
| a a fo | he reply was filed after a final rejection, but prior to or on the sar pplication, applicant must timely file one of the following replies: pplication in condition for allowance; (2) a Notice of Appeal (with or Continued Examination (RCE) in compliance with 37 CFR 1.1 | : (1) an amendment, affidavit, or other evidence, which places t h appeal fee) in compliance with 37 CFR 41.31; or (3) a Reque | he |
| a) [b) 2 | no event, however, will the statutory period for reply expire later than | Action, or (2) the date set forth in the final rejection, whichever is later. | |
| have be under 3 set forth may red | ons of time may be obtained under 37 CFR 1.136(a). The date on which then filed is the date for purposes of determining the period of extension at 7 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened in (b) above, if checked. Any reply received by the Office later than threshold any earned patent term adjustment. See 37 CFR 1.704(b). IE OF APPEAL | and the corresponding amount of the fee. The appropriate extension feed statutory period for reply originally set in the final Office action; or (2) | ee as |
| 2. 🔲 T fi N | The Notice of Appeal was filed on A brief in compliance valing the Notice of Appeal (37 CFR 41.37(a)), or any extension the lotice of Appeal has been filed, any reply must be filed within the DMENTS | nereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since | |
| 3. 🔯 · (a (l | The proposed amendment(s) filed after a final rejection, but prior a) They raise new issues that would require further considerated. They raise the issue of new matter (see NOTE below); They are not deemed to place the application in better form | tion and/or search (see NOTE below); | |
| (d)⊠ 1 | appeal; and/or d) ☑ They present additional claims without canceling a corresponding NOTE: See Continuation Sheet. (See 37 CFR 1.116 and The amendments are not in compliance with 37 CFR 1.121. See | 41.33(a)). | |
| 5. | Applicant's reply has overcome the following rejection(s): Newly proposed or amended claim(s) would be allowable on-allowable claim(s). | | he |
| 7. X F h T C C C C | For purposes of appeal, the proposed amendment(s): a) will ow the new or amended claims would be rejected is provided be the status of the claim(s) is (or will be) as follows: Claim(s) allowed: Claim(s) objected to: Claim(s) rejected: 5 and 15-19. Claim(s) withdrawn from consideration: | | |
| | AVIT OR OTHER EVIDENCE | | |
| b w | he affidavit or other evidence filed after a final action, but before ecause applicant failed to provide a showing of good and sufficional not earlier presented. See 37 CFR 1.116(e). | ient reasons why the affidavit or other evidence is necessary ar | nd |
| е | The affidavit or other evidence filed after the date of filing a Notice intered because the affidavit or other evidence failed to overcom howing a good and sufficient reasons why it is necessary and wa | ne <u>all</u> rejections under appeal and/or appellant fails to provide a | 1 |
| <u>REQUI</u> | The affidavit or other evidence is entered. An explanation of the EST FOR RECONSIDERATION/OTHER | · | |
| | The request for reconsideration has been considered but does Name See Continuation Sheet. Note the attached Information Disclosure Statement(s). (PTO/SI | | |
| | Other: | 15/100/1 apol 110(3) | |
| | derick Krass/ rvisory Patent Examiner, Art Unit 1612 | /Walter E Webb/ Examiner, Art Unit 1612 | |
| | | | |

Continuation of 3. NOTE: Applicant has amended claim 5 such that the limitation "or for the prolongation of graft survival" has been removed. Claim 5 was previously rejected over this limitation. An new search and consideration would have to be made to address the newly amended claim.

Continuation of 11. does NOT place the application in condition for allowance because: Applicants argument with regard to the amendments after final are moot and will not be addressed here since the amendments will not be entered. In regard to treatment of GVHD, appliant argues that since RO32-0432 of Goekjian, which is taught to be used for treating GVHD, is not an indolylmaleimide, one would not substitute the comounds of Heath for RO32-0432 to treat GVHD. However, the rejection over Goekjian does not hinge on the structural relationship of the RO32-0432 and the compounds of Heath. The teaching of Goekjian was used more for evidentiary purposes to further establish a link between the isozyme selectivity for PKC and the treatment GVHD. Given that GVHD is recognized as a PKC-linked immunodiorder and the compounds of Heath are used for treating PKC-linked immunodisorders, the artisan would have a reasonable expectation of success in treating GVHD with the compounds of Heath.

Applicant continues to argue that the since the compounds of Heath are inhibitors of PKC beta 1 and 2, the artisan would not have a reasonable expectation of success for treating GVHD. However, the art of record shows that inhibitors of the PKC beta isoforms are useful for treating GVHD.